

Charles H. Chevalier
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102-5310
(973) 596-4611
cchevailier@gibbonslaw.com

Christine A. Gaddis
GIBBONS P.C.
141 West Front Street, Suite 240
Red Bank, New Jersey 07701
(732) 704-5801
cgaddis@gibbonslaw.com

*Attorneys for Plaintiff
American Regent, Inc.*

OF COUNSEL:

Dennies Varughese, Pharm. D.
Uma Everett
Adam LaRock
Christina Dashe
Alex Alfano
Ryan Conkin
Sterne, Kessler, Goldstein & Fox P.L.L.C.
1101 K Street, NW, 10th Floor
Washington, DC 20005
(202) 371-2600
dvarughese@sternekessler.com
ueverett@sternekessler.com
alarock@sternekessler.com
cdashe@sternekessler.com
aalfano@sternekessler.com
rconkin@sternekessler.com

**IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

IN RE SELENIOUS ACID LITIGATION

C.A. No. 2:24-cv-07791 (BRM) (CLW)
(Consolidated)

**PLAINTIFF'S ANSWER TO DEFENDANTS CIPLA LIMITED AND CIPLA USA,
INC.'S ANSWER AND COUNTERCLAIMS TO PLAINTIFF'S COMPLAINT**

Plaintiff/Counterclaim Defendant American Regent, Inc. ("ARI"), by its undersigned attorneys, hereby responds to the Answer, Affirmative Defenses, and Counterclaims of Defendants/Counterclaimants Cipla Limited and Cipla USA, Inc. ("Cipla") (ECF No. 69; hereinafter, the "Counterclaims") as follows:

GENERAL DENIAL

ARI denies all allegations in Cipla's Counterclaims except for those specifically admitted

below. With respect to the allegations made in the Counterclaims, upon knowledge with respect to ARI's own acts, and upon information and belief as to other matters, ARI responds and alleges as follows:

THE PARTIES

1. Counterclaim-Plaintiff Cipla Limited is a corporation organized and existing under the laws of India, having its corporate office at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai Maharashtra 400013, India.

ANSWER: On the basis of Cipla's Answer to Paragraph 3 in the Counterclaims, admitted.

2. Counterclaim-Plaintiff Cipla USA is a corporation organized and existing under the laws of Delaware, having its principal place of business at 10 Independence Boulevard, Suite 300, Warren, NJ 07059. Cipla USA is an indirect subsidiary of Cipla Limited.

ANSWER: On the basis of Cipla's Answer to Paragraph 4 in the Counterclaims, admitted

3. On information and belief, Counterclaim-Defendant American Regent, Inc. ("ARI") is a corporation organized and existing under the laws of the State of New York, with a principal place of business at 5 Ramsey Road, Shirley, New York 11967.

ANSWER: Admitted.

JURISDICTION AND VENUE

4. These counterclaims arise under the Patent Laws of the United States, 35 U.S.C. §100, *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338, 2201, and 2202.

ANSWER: Paragraph 4 states legal conclusions for which no response is required. To the extent a response is required, ARI admits that Cipla purports to bring the Counterclaims under the patent laws of the United States and 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202. ARI does not contest subject matter jurisdiction in this judicial district for the purposes of this action only. ARI denies that the Counterclaims have merit or that Cipla is entitled to any relief on its Counterclaims.

5. Personal jurisdiction over the Plaintiff/Counterclaim-Defendant exists because the Plaintiff/Counterclaim-Defendant has submitted to the personal jurisdiction of the Court.

ANSWER: Paragraph 5 states legal conclusions for which no response is required. To the extent a response is required, ARI does not contest personal jurisdiction for purposes of this action only. ARI otherwise denies the allegations of Paragraph 5.

6. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400.

ANSWER: Paragraph 6 states legal conclusions for which no response is required. To the extent a response is required, ARI does not contest venue in this judicial district for the purposes of this action only. ARI otherwise denies the allegations of Paragraph 6.

FACTUAL BACKGROUND

The Patents-in-Suit

7. On December 13, 2024, Plaintiff/Counterclaim-Defendant filed a Complaint alleging, *inter alia*, infringement of United States Patent No. 12,150,957 (the “’957 patent”).

ANSWER: Admitted.

8. Prior to the filing of this action, upon information and belief, Plaintiffs/Counterclaim-Defendants listed and caused to be listed the ’957 patent in the publication of the Federal Food and Drug Administration (“FDA”) entitled “Approved Drug Products for Therapeutic Equivalents Evaluations” (commonly known as the “Orange Book”) for NDA No. 209379.

ANSWER: Admitted.

9. The ’957 patent is entitled, “Trace element compositions, methods of making and use,” and indicates on the face of that patent that it issued on November 26, 2024.

ANSWER: Admitted.

10. Upon information and belief, Plaintiff/Counterclaim-Defendant is listed as the owner by assignment of the ’957 patent in the U.S. Patent and Trademark assignment database.

ANSWER: Admitted.

Cipla’s Notice Letter and ARI’s Suit

11. Cipla has filed with the FDA an Abbreviated New Drug Application (“ANDA”) bearing No. 218661, seeking to obtain approval to engage in the commercial manufacture, use, sale, or importation of a proposed generic trace element nutrition product containing selenious acid in three dosage strengths: ((1) eq. 600 mcg Selenium/10 mL (eq. 60 mcg Selenium/mL) and (2) eq. 12 mcg Selenium/2 mL (eq. 6 mcg Selenium/mL)) (“Cipla’s ANDA Product”).

ANSWER: ARI admits that, by letter dated January 3, 2025, (the “Cipla Notice Letter”), Cipla notified ARI that Cipla submitted ANDA No. 218661 to market generic versions of selenious acid solutions, intravenous, 600 mcg Selenium/10 mL (eq. 60 mcg Selenium/mL) and 12 mcg Selenium/2 mL (eq. 6 mcg Selenium/mL). ARI otherwise denies the allegations in Paragraph 11.

12. Pursuant to 21 U.S.C. § 355(j)(2)(A)(iv), Cipla’s ANDA No. 218661 contains a “Paragraph IV” certification stating that the ’957 patent is invalid or will not be infringed by the manufacture, use, sale, offer to sell, or importation into the United States of the proposed drug product which is the subject of Cipla’s ANDA No. 218661.

ANSWER: ARI admits that the Cipla Notice Letter notified ARI that Cipla submitted ANDA No. 218661 to market a generic version of Selenious Acid Injection USP prior to the expiration of the ’957 patent. ARI further admits that the Cipla Notice Letter contained arguments and/or positions that the ’957 patent is invalid and/or not infringed, which are not grounded in fact or law and raise material issues to be resolved in later stages in this proceeding, including claim construction issues and patent infringement and validity issues that will be the subject of fact and expert discovery, neither of which have occurred. ARI denies that Cipla’s factual and legal bases have merit. ARI otherwise denies the allegations in Paragraph 12.

13. Pursuant to the applicable statutes, rules, and regulations, Cipla notified Plaintiff/Counterclaim-Defendant that it had submitted to the FDA a Paragraph IV certification regarding the ’957 patent related to ANDA No. 218661 for Cipla’s ANDA Product by letter dated January 3, 2025 (“Cipla’s ’957 Patent Notice Letter”).

ANSWER: ARI admits that the Cipla Notice Letter notified ARI that Cipla submitted ANDA No. 218661 to market a generic version of Selenious Acid Injection USP prior to the expiration of the ’957 patent. ARI further admits that the Cipla Notice Letter contained arguments and/or positions that the ’957 patent is invalid and/or not infringed, which are not grounded in fact

or law and raise material issues to be resolved in later stages in this proceeding, including claim construction issues and patent infringement and validity issues that will be the subject of fact and expert discovery, neither of which have occurred. ARI denies that Cipla's factual and legal bases have merit. ARI otherwise denies the allegations in Paragraph 13.

14. Plaintiff/Counterclaim-Defendant filed their Complaint against Cipla alleging infringement of the '957 patent on December 13, 2024.

ANSWER: Admitted.

15. By virtue of Plaintiff/Counterclaim-Defendant having listed the '957 patent in the Orange Book, by virtue of Cipla's submission of a "Paragraph IV" certification regarding this patent and providing Plaintiff/Counterclaim-Defendant with notice and the basis for such certification, and/or by virtue of the Complaint filed herein, an actual case and controversy exists between Cipla and Plaintiff/Counterclaim-Defendant as to the infringement and validity of the '957 patent.

ANSWER: Paragraph 15 states legal conclusions for which no response is required. To the extent a response is required, ARI admits there is a present, genuine, and justiciable controversy that exists between ARI and Cipla regarding Cipla's infringement of the '957 patent. ARI specifically denies that there is a present, genuine, and justiciable controversy regarding invalidity of the '957 patent.

16. Cipla does not infringe any valid and enforceable claim of the '957 patent, either directly or indirectly.

ANSWER: Denied.

17. An actual and justiciable controversy exists between Plaintiff/Counterclaim-Defendant and Cipla relating to, *inter alia*, the '957 patent.

ANSWER: Paragraph 17 states legal conclusions for which no response is required. To the extent a response is required, ARI admits there is a present, genuine, and justiciable controversy that exists between ARI and Cipla regarding Cipla's infringement of the '957 patent.

COUNT I

(Declaratory Judgment of Invalidity – U.S. Patent No. 12,150,957)

18. Cipla repeats and realleges each of the foregoing paragraphs of the counterclaim as if fully set forth herein.

ANSWER: No response is required to the general re-allegation and incorporation by reference of the foregoing paragraphs of the Counterclaims. To the extent a response is required, ARI incorporates the answers in response to the foregoing paragraphs as if fully set forth herein.

19. There is an actual, substantial, and continuing justiciable case or controversy between Cipla and ARI regarding the invalidity of the '957 patent.

ANSWER: Paragraph 19 states legal conclusions for which no response is required. To the extent a response is required, ARI admits there is a present, genuine, and justiciable controversy that exists between ARI and Cipla regarding Cipla's infringement of the '957 patent. ARI specifically denies that there is a present, genuine, and justiciable controversy regarding invalidity of the '957 patent.

20. The '957 patent is invalid for failing to satisfy one or more of the conditions for patentability set forth in 35 U.S.C. §§ 101, *et seq.*, including without limitation, 35 U.S.C. §§ 101, 102, 103, 112, 116, 120, non-statutory (obviousness-type) double patenting, the defenses recognized in 34 U.S.C. § 282(b) and/or any other judicially created bases for invalidity.

ANSWER: Denied.

21. The '957 patent is invalid for the reasons set forth in Cipla's '957 Patent Notice Letter.

ANSWER: Denied.

22. Cipla is entitled to a declaratory judgment that the claims of the '957 patent are invalid.

ANSWER: Denied

COUNT II

(Declaratory Judgment of Non-Infringement – U.S. Patent No. 12,150,957)

23. Cipla repeats and realleges each of the foregoing paragraphs of the counterclaim as if fully set forth herein

ANSWER: No response is required to the general re-allegation and incorporation by reference of the foregoing paragraphs of the Counterclaims. To the extent a response is required, ARI incorporates the answers in response to the foregoing paragraphs as if fully set forth herein.

24. There is an actual, substantial, and continuing justiciable case or controversy between the Cipla parties and ARI regarding the non-infringement of the '957 patent.

ANSWER: Paragraph 24 states legal conclusions for which no response is required. To the extent a response is required, ARI admits there is a present, genuine, and justiciable controversy that exists between ARI and Cipla regarding Cipla's infringement of the '957 patent.

25. For at least for the reasons set forth in Cipla's '957 Patent Notice Letter, Cipla's manufacture, use, offer for sale, sale, and/or importation into the United States of Cipla's ANDA Product upon FDA approval to do so pursuant to ANDA No. 218661 has not and will not infringe, directly or indirectly, any valid and enforceable claim of the '957 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

26. Cipla does not and has not committed any acts in violation of 35 U.S.C. § 271.

ANSWER: Denied.

27. Cipla is entitled to a declaratory judgment that its manufacture, use, offer for sale, and/or importation into the United States of Cipla's ANDA Product pursuant to ANDA No. 218661 has not and will not infringe, directly or indirectly, any valid and enforceable claim of the '957 Patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

PRAYER FOR RELIEF

ARI denies that Cipla is entitled to any judgment or relief against ARI and, therefore specifically denies Paragraphs (A)–(G) of Counterclaimant Cipla's Prayer for Relief.

Each averment and/or allegation contained in Cipla's Counterclaims that is not specifically admitted herein is hereby denied.

ARI requests that judgment be entered in its favor, dismissing Cipla's Counterclaims with prejudice, awarding ARI's attorneys' fees and costs incurred in this litigation under 35 U.S.C. §

285, and granting even further relief as the Court may deem just and proper.

Dated: January 28, 2025

By: s/ Charles H. Chevalier
Charles H. Chevalier
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102-5310
(973) 596-4611
cchevailier@gibbonslaw.com

Christine A. Gaddis
GIBBONS P.C.
141 West Front Street, Suite 240
Red Bank, New Jersey 07701
(732) 704-5801
cgaddis@gibbonslaw.com

OF COUNSEL:

Dennies Varughese, Pharm. D.
Uma Everett
Adam LaRock
Christina Dashe
Alex Alfano
Ryan Conkin
Sterne, Kessler, Goldstein & Fox P.L.L.C.
1101 K Street, NW, 10th Floor
Washington, DC 20005
(202) 371-2600
dvarughese@sternekessler.com
ueverett@sternekessler.com
alarock@sternekessler.com
cdashe@sternekessler.com
aalfano@sternekessler.com
rconkin@sternekessler.com

*Attorneys for Plaintiff
American Regent, Inc.*

CERTIFICATE OF SERVICE

I hereby certify that on January 28, 2025, a true and correct copy of Plaintiff's Answer to Defendants Cipla Limited and Cipla USA, Inc.'s Answer and Counterclaims to Plaintiff's Complaint was served by ECF on all counsel of record and electronic mail on all counsel of record for Cipla.

Date: January 28, 2025

s/ Charles H. Chevalier

Charles H. Chevalier